Department of Veterans Affairs

Memorandum

Date: August 8, 2006

From: Stratton VAMC Research & Development

Subj: Posting a Research Participant Enrollment Note into the Electronic Medical Record (EMR)

To: Clinical Investigators

(This supercedes the EMR Memorandum dated May 9, 2005.)

A posting is not required in the medical record if the research involves no more than minimal risk and the research subject's participation involves:

1. only one encounter (i.e. healthy volunteer blood draw),
2. only the use of a questionnaire,
3. the use of previously collected biological specimens, or
4. the ability to identify a patient as a participant in a particular study places the participant at greater than minimal risk.

Investigators should document these research activities in the investigator's research case history file. All other exceptions from documentation in the medical record are at the discretion of the IRB upon request of the Principal Investigator.

A. Research Study Initiation Note - Once this note is signed, it will appear in the participant's EMR under "CLINICAL WARNING" in the upper right corner of the cover sheet.

Procedure:

1. Access the participant's EMR.
2. Click on the "NOTES" tab.
3. Click on "NEW NOTE".
4. Click on "RESEARCH STUDY INITIATION NOTE ".
5. Enter the following required information:
   a. Title of the research study.
   b. Name of Principal Investigator, study coordinator, and other relevant study personnel.
   c. The name of the individual obtaining informed consent and date informed consent was obtained.
   d. Contact information in case of emergency or need for further information regarding protocol therapy. This should include both day-time and off-tour phone numbers.
   e. Inclusion and exclusion criteria and documentation that the research participant meets these criteria.
   f. A statement that the research subject had capacity to consent and comprehension of the research study or that a legally authorized representative of the patient gave consent.

B. **Research Study Progress Note** – This note is used to document each study visit, including the "enrollment visit".
    1. Include the actual date that the participant was enrolled into the study (this date may or may not be identical to the date that informed consent was obtained).
    2. Include all data appropriate to the study as well as a review of the participant's laboratory and clinical status indicating that the participant is still appropriate for the study.
    3. Include a statement that the subject or the subject's legally authorized representative continued to comprehend and consent to the research process.

C. **Research Study Termination Note** – This note is required for all participants who have a "Research Initiation" note and is to be added as an addendum to the "Research Initiation" note. This note should:
    1. be written when the participant has completed the study,
    2. include the date that the participant's study involvement ended,
    3. include any other information appropriate to the study.

D. **Encounter Location-** For research studies that involve participant visits that are due to research participation only and are not part of standard care, the PI should contact HIMS to designate a specific "Research" encounter designation to be used when entering the encounter information. This is to ensure that research participants do not receive a bill from the VAMC for these visits due solely for the research.

Thank you for your cooperation.

Raymond P. Smith, M.D
Acting ACOS for Research and Development